IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BELCHER PHARMACEUTICALS, LLC	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 17-775-LPS
	:	
HOSPIRA, INC.,	:	
	:	
Defendant.	:	
	:	

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MEMORANDUM OPINION

September 28, 2018
Wilmington, Delaware

STARK, U.S. District Judge:

This is a patent infringement case arising under the Hatch-Waxman Act. According to the complaint, Plaintiff Belcher Pharmaceuticals, LLC ("Belcher") holds approved New Drug Application ("NDA") No. 205029 for Epinephrine Injection USP, 1 mg/ml, which is prescribed and sold in the United States. (D.I. 1 ¶ 13) Defendant Hospira, Inc. ("Hospira") submitted NDA No. 209359 to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, or sale of Epinephrine Injection USP, Abboject™ Syringe 1mg/10mL (the "NDA Product") in the United States. (*Id.* ¶ 8) Belcher sued Hospira, alleging that any future manufacture or sale of Hospira's NDA Product, once it is approved by the FDA, would infringe Belcher's patent, U.S. Patent No. 9,283,197 ("'197 patent").[1] (*See id.* ¶ 24) The patent discloses "pharmaceutical formulations of levorotatory-epinephrine, l-epinephrine, more potent and less toxic than existing pharmaceutical formulations of epinephrine, along with methods of producing and using these pharmaceutical formulations of l-epinephrine." '197 patent, Abstract.

Presently before the Court is the parties' dispute over the meaning of certain claim terms in the '197 patent. The parties submitted claim construction briefs (*see* D.I. 69, 70, 79, 80), and expert declarations (*see* D.I. 71, 74). The Court held a claim construction hearing on April 11, 2018, at which both sides presented oral argument and live testimony from their respective experts. (*See* D.I. 87 ("Tr."); D.I. 85, 86)

[1]A copy of the '197 patent is attached as Exhibit A to the complaint (D.I. 1).

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted).

"[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide. . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the

invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

III. CONSTRUCTION OF DISPUTED TERMS[2]

A. "compounded in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine"

Plaintiff "having 1.0 to 1.06 mg/mL l-epinephrine in an aqueous solution at any point during preparation"
Defendant *See* "said injectable liquid formulation compounded", "in an aqueous solution", and "as 1.0 to 1.06 mg/mL l-epinephrine"
Court "having 1.0 to 1.06 mg/mL l-epinephrine in an aqueous solution after the compounding step has been completed"

The parties dispute whether the claimed concentration range of epinephrine (1.0 to 1.06 mg/mL) refers to the concentration range at the end of the compounding step (Defendant's position) or to the concentration range at any time during the compounding step (Plaintiff's position).[3] Plaintiff contends that "the compounding process is a (1) distinct step (2) which takes

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[2]All the disputed claim terms are present in claim 6, the only asserted independent claim. (*See* D.I. 69 at 2)

[3]The parties also dispute the significance of the patent's use of the past tense ("compounded") and present tense ("compounding") of the word "compound." (*See* D.I. 69 at 9-11; D.I. 70 5-6, 9, 13; D.I. 79 at 2-4; D.I. 80 at 10, 18-20)

time and (3) has varying concentrations of l-epinephrine from start to finish." (D.I. 69 at 6) While Defendant does not the dispute Plaintiff's characterization of the compounding process,[4] Defendant contends that the claim language refers to "the characteristics of the solution ***after the compounding step has been completed***." (D.I. 70 at 13) (emphasis in original) The Court agrees with Defendant.

Plaintiff's main argument is that "claim 6 refers to the varying concentrations of l-epinephrine at various points during the compounding process." (D.I. 79 at 1) But the intrinsic evidence does not support Plaintiff's position. The specification identifies a single concentration of epinephrine during the compounding step. *See* '197 patent at 3:29-31; 4:61-63 (noting either 1.1 mg or 1.03 mg of epinephrine base "per mL" of compounded solution). The prosecution history also describes the compounding step as having a narrow concentration range relative to the concentration in the final product. (*See* D.I. 63-3 at pp. 2-3 of 6)[5] While the Court understands that the compounding step of a drug product may involve many intermediate steps (*see* D.I. 71 ¶¶ 21, 31-36), and potentially the drug product could have different concentrations at different steps of the compounding step, the specification makes no reference to any intermediate steps during compounding, nor does it identify specific epinephrine concentrations during such steps.

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[4]Defendant agrees that compounding is a distinct step in the manufacturing process and takes time. (D.I. 80 at 3) Defendant also does not dispute the epinephrine concentration could potentially change from start to finish during the compounding step. (*See* D.I. 70 at 17) (explaining that "compounding of a drug product can also involve the preparation of intermediate solutions")

[5]The Court is persuaded by Defendant's expert's opinion that adopting Plaintiff's construction would be inconsistent with this portion of the prosecution history. (*See* D.I. 71 at 15 ¶ 36)

The Court credits Defendant's expert's opinion that, for purposes of evaluating the concentration of any particular component in the claimed formulation, a person of ordinary skill in the art ("POSA") would consider only the final concentration at the end of the compounding step after all the relevant components have been added and mixed together, rather than the concentration at any and all times during the compounding step.[6] (*See id.*) The Court also finds persuasive Defendant's expert's opinion about overages, as described in the patent; the claimed invention makes it possible to prepare an epinephrine formulation with reduced overages, *see* '197 patent at 4:58-59; 5:4-6, or even with no overage, *see id.* at 5:23-26.[7] Defendant's expert explains that "an overage can only refer to excess drug product ***after compounding is complete*** . . . because there can be no overage until all components are in their final concentrations." (D.I. 71 ¶¶ 33, 34) (emphasis in original).

Plaintiff's claim differentiation argument does not lead to a different conclusion. Plaintiff contends that "[c]laim differentiation shows that the plain language of claims 6 and 7 requires a distinct compounding step." (D.I. 69 at 6-7) Plaintiff contends that claim 6 refers to the concentration during the compounding process, while claim 7 refers to the concentration of the

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[6]Plaintiff's expert cites to the specification, which explains that the claimed formulation could be made in larger volumes using different sized containers, *see* 197 patent at 5:8-14, and concludes that this means that the formulation could be compounded in many different concentrations, *see* D.I. 74 ¶ 28. Plaintiff's expert also summarizes the compounding process of the epinephrine formulation according to Defendant's NDA and concludes that the NDA product "will have a concentration of 1.0 to 1.06 mg/mL l-epinephrine at some point during [this] process." (*Id.* at ¶ 30) The Court is not persuaded by Plaintiff's expert's opinion, which appears to conflate the amount of epinephrine (e.g., 1 mg) with concentration of epinephrine (e.g., 1 mg/mL).

[7]These overages correspond to the claim language. Claims 1, 4, and 6, which are drawn to formulations compounded as 1.0 to 1.06 mg/mL l-epinephrine, represent "less or no more than a 6% overage," while claims 2 and 5, which are drawn to formulations compounded as 1.03 mg/mL epinephrine, represent "preferably a 3% overage." (D.I. 71 ¶ 33)

final product. (*See id.* at 7) The Court agrees with Defendant that while these "two concentrations are distinct" (D.I. 80 at 20), they are not distinct in a way that supports Plaintiff. Instead, as Defendant writes: "While dependent claim 7 indeed describes the epinephrine concentration in a final product – a '1 mg per mL, epinephrine" formulation – claim 6 is drawn to the properties of that product as compounded, *i.e.*, at the end of the compounding step" (*id.* at 7) (internal citation omitted). Both claims are directed to periods after compounding is complete. Thus, the distinction between claims 6 and 7 supports Defendant's view that, as claimed in the patent, the concentration of import is the concentration ***after*** the compounding process is complete.

The Court has also considered Plaintiff's characterization of its patent as a "pioneer" patent, and its argument that such a patent is entitled to a broad construction, and finds it unavailing in the context of the particular disputes before the Court.[8]

B. "said injectable liquid pharmaceutical formulation compounded"

Plaintiff *See* "compounded in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine"
Defendant "the injectable liquid pharmaceutical formulation formed by combining the active ingredients and excipients"
Court "the injectable liquid pharmaceutical formulation formed by combining the active ingredients and excipients"

Plaintiff contends that Defendant's construction would render the term indefinite, as a

[8]Giving the Court's findings of fact and conclusions of law, as expressed in the above analysis, it is unnecessary to resolve the parties' disputes as to indefiniteness (*see* D.I. 69 at 9-10; D.I. 70 at 18-20) and recapture of disavowed and disclaimed claim scope (D.I. 71 at 16-18).

POSA would not be able to understand the meaning of "the active ingredients and excipients," as they lack proper antecedent basis. (D.I. 69 at 10) Plaintiff further contends that Defendant's use of the word "formed" is confusing, lacks support in intrinsic evidence, changes the claim's scope, and imposes limitations from dependent claims into independent claims. (*Id.* at 11) Defendant counters that its construction uses commonly-understood words in the relevant art and is consistent with how a POSA would understand the meaning of the term. (*See* D.I. 80 at 16, 18) The Court agrees with Defendant.

The patent explains that the compounding step involves mixing the components of the formulation in an appropriate solvent. *See* '197 patent, 3: 15-42. The patent also explains that the active pharmaceutical ingredient in the formulation is l-epinephrine; the word excipient is not in the patent. *Id.* at 3:15-17. Contrary to Plaintiff's assertions, however, active ingredients and excipients are common words used to generally describe the components of a formulation in the pharmaceutical arts. Even Plaintiff's expert agreed that the compounding step "is the combination of the active ingredients and the excipient[s]." (D.I. 80 Ex. A at 115) He further testified that a POSA would understand the meaning of those words and specifically identified what those are in the asserted patent. (*See id.* at 94-95) (agreeing that POSA would know what active ingredient and excipient means and identifying, in asserted patent, epinephrine as active ingredient and hydrochloride and sodium chloride as excipients)

C. "in an aqueous solution"

Plaintiff *See* "compounded in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine"
Defendant "in a homogenous mixture of one or more substances dissolved in a solvent that is mainly water"
Court "in a homogenous mixture of one or more substances dissolved in a solvent that is mainly water"

The parties dispute whether this term refers to a solution in which the relevant components are completely dissolved in the solvent, as Defendant contends (D.I. 70 at 8-11), or to a solution in which the components need not be completely dissolved in the solvent, as Plaintiff contends (D.I. 79 at 7).[9] Plaintiff argues that "there will be an uneven distribution of l-epinephrine particles throughout the mixing tank " under certain circumstances when the components are mixed together at the compounding step.[10] (*See* D.I. 79 at 7) Defendant argues that its construction is consistent with the customary meaning of the term in the relevant art and with the intrinsic evidence. (D.I. 70 at 8-11) The Court agrees with Defendant.

According to the patent, the preparation of the claimed formulation includes "the compounding of the drug substance, followed by initial filtration, filling and sterilization." '197 patent at 3:6-9. The patent explains that the "compounding step was performed to place the

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[9]There is no dispute that "aqueous" refers to a solution in which solvent primarily consists of water. (*See id.* at 7; *see also* '197 patent at 3:20 ("Water for injection was the solvent."))

[10]Plaintiff also argues that Defendant's construction improperly uses the word "dissolved" in the past tense. (D.I. 69 at 11-12; D.I. 79 at 7) But Plaintiff has not persuasively explained, nor is it clear to the Court, how the tense of the word is critical to understanding the meaning of the term from a POSA's viewpoint.

solid/powder active pharmaceutical ingredient into aqueous solution," and the purpose of filtration is to remove "any particulates, whether bacterial or undissolved ingredients." *Id.* at 3:17-19; 3:44-46. While the patent does not provide any definition of an aqueous solution, the Court credits Defendant expert's opinion that a POSA would understand an aqueous solution to be a solution consisting of a homogenous mixture of one or more components in which "the components are uniformly distributed." (D.I. 71 ¶ 26) In the Court's view, the removal of any undissolved ingredients during the filtration step, as described in the patent, is not inconsistent with Defendant's expert's opinion.

D. "as 1.0 to 1.06 mg/mL l-epinephrine"

Plaintiff *See* "compounded in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine"
Defendant "the concentration of l-epinephrine in the compounded solution being within the range of 1.0 to 1.06 mg/mL"
Court "the concentration of l-epinephrine in the compounded solution being within the range of 1.0 to 1.06 mg/mL"

Plaintiff contends that Defendant's construction lacks antecedent basis, and is thus indefinite, because it is not clear whether "the compounded solution" in claim 6 refers to "the injectable pharmaceutical formulation" or to "a homogenous mixture" under Defendant's proposed constructions.[11] (D.I. 69 at 12) Defendant responds that in both instances in which "compounded solution" is mentioned in the specification, it refers to the end result of the compounding step. (D.I. 18 at 17) The Court agrees with Defendant.

[11]Plaintiff also argues that Defendant's construction improperly uses "compounded" in the past tense. It is unclear how use of the past tense incorrectly influences the meaning of the term.

The patent explains that "these injectable liquid pharmaceutical formulations of l-epinephrine sterile solution introduced by this invention . . . are preferably compounded in an aqueous solution as approximately 1.0 to 1.06 mg/mL l-epinephrine." '197 patent, 5:36-41. Additionally, during prosecution, the applicant explained that "the approximately 1.0 to 1.06 mg/mL l-epinephrine describes how the formulation is ***compounded*** during manufacturing; a narrow concentration range during the production step of compounding." (D.I. 63-3 at p. 2 of 6) (emphasis in original) Thus, the intrinsic evidence makes clear that the specified concentration refers to the concentration range of epinephrine during the compounding step. The Court also agrees with Defendant that this concentration range refers to the concentration after the compounding step has been completed, as discussed earlier.

E. "and further including a tonicity agent"

Plaintiff No construction is necessary
Defendant "the compounded solution including a tonicity agent"
Court No construction is necessary

The dispute is whether a tonicity agent is added to the formulation after the compounding step has been completed, as Defendant contends (D.I. 70 at 12), or whether it is added during the compounding step, as Plaintiff contends (D.I. 69 at 13). The Court agrees with Plaintiff. The plain meaning of the term is evident to a POSA from reading the specification, which makes clear that the tonicity agent (e.g., sodium chloride) is added during the compounding step. *See* '197 patent, 3:15-34. Defendant's construction does not add anything meaningful and is unhelpful.

IV. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.